IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: PARAGARD IUD PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 2974 1:20-md-02974-LMM
This document relates to: Pauline Rickard Melody Braxton Alisa Robere	:	CIVIL ACTION NOs.: 1:21-cv-03861-LMM [45] 1:22-cv-00490-LMM [43] 1:22-cv-01583-LMM [53]

ORDER

This multi-district litigation ("MDL") involves the contraceptive Paragard, an intrauterine device ("IUD"), which is regulated as a drug under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and the federal Food and Drug Administration's ("FDA") implementing regulations in Title 21 of the Code of Federal Regulations. The case is presently before the Court on a motion for summary judgment of the failure-to-warn claims asserted against Defendant CooperSurgical, Inc. ("Cooper") by bellwether plaintiffs Pauline Rickard, Melody Braxton, and Alisa Robere (collectively, "Plaintiffs").[1] The Court held oral argument on the motion on November 20, 2025. After due consideration, the Court enters the following Order.

[1] The Court ruled on the other issues raised in the motion for summary judgment in separate Orders. See Ords., Nov. 21, 2025, Dec. 19, 2025.

I. LEGAL STANDARD

Rule 56 of the Federal Rules of Civil Procedure provides that "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A factual dispute is genuine if the evidence would allow a reasonable jury to find for the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A fact is "material" if it is "a legal element of the claim under the applicable substantive law which might affect the outcome of the case." Allen v. Tyson Foods, Inc., 121 F.3d 642, 646 (11th Cir. 1997).

The moving party bears the initial burden of showing the Court, by reference to materials in the record, that there is no genuine dispute as to any material fact that should be decided at trial. Hickson Corp. v. N. Crossarm Co., 357 F.3d 1256, 1260 (11th Cir. 2004) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986)). The moving party's burden is discharged merely by " 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support [an essential element of] the nonmoving party's case." Celotex Corp., 477 U.S. at 325. In determining whether the moving party has met this burden, the district court must view the evidence and all factual inferences in the light most favorable to the party opposing the motion. Johnson v. Clifton, 74 F.3d 1087, 1090 (11th Cir. 1996).

Once the moving party has adequately supported its motion, the non-movant then has the burden of showing that summary judgment is improper by coming forward with specific facts showing a genuine dispute. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.' " Id. "The mere existence of a scintilla of evidence" supporting the non-movant's case is insufficient to defeat a motion for summary judgment. Anderson, 477 U.S. at 252. All reasonable doubts, however, are resolved in favor of the non-movant. Fitzpatrick v. City of Atlanta, 2 F.3d 1112, 1115 (11th Cir. 1993).

II. BACKGROUND

A. Facts

Paragard is an IUD that is implanted into a patient by a healthcare provider. It is a T-shaped device that is made of polyethylene milled with barium sulfate and wrapped in copper. It is indicated for intrauterine contraception for up to 10 years. The T-shape is designed to collapse for insertion and removal. It is supposed to be easy for a healthcare practitioner to remove the Paragard by gently pulling on attached threads.

Paragard has been approved and regulated by the FDA since 1984 without any significant design updates. Teva[2] became the owner of the Paragard NDA in December 2008. Cooper acquired the Paragard NDA from Teva on November 1, 2017.

Robere underwent placement of a Paragard in June 2011, Rickard had hers placed in May 2012, and Braxton had hers placed in November 2014. At the time Plaintiffs had their Paragards placed, there was nothing in the Warnings, Adverse Reactions, or Patient Information sections of the drug label about breakage, and each plaintiff expected to have a follow-up procedure to have the Paragard removed per the removal instructions on the label. But in each case—when Robere and Braxton had their Paragards removed in or around December 2019 and when Rickard had hers removed in August 2021—the Paragard was broken, and it was necessary for the plaintiff to have surgery to remove fragments of the Paragard.

B. Procedure

The bellwether plaintiffs asserted twelve claims against Defendants, all under state[3] law: Strict Liability—Design Defect (Count I); Strict Liability—

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[2] For the purposes of this Order, "Teva" refers to Cooper's co-defendants, Teva Pharmaceuticals USA, Inc., Teva Women's Health, LLC, and Teva Branded Pharmaceutical Products R&D, Inc.

[3] The parties have determined that Florida law applies to the claims of each of the bellwether plaintiffs, except as to Rickard's claim for punitive damages, which she contends is governed by New York law.

Failure to Warn (Count II); Negligence (Count IV); Negligence—Design Defect (Count V); Negligence—Failure to Warn (Count VI); Fraud & Deceit (Count VII); Fraud by Omission (Count VIII); Negligent Misrepresentation (Count IX); Breach of Express Warranty (Count X); Breach of Implied Warranty (Count XI); Gross Negligence (Count XIII); and Punitive Damages (Count XV).[4]

In separate Orders, the Court granted summary judgment in favor of Cooper on the claims grounded in allegations of design defect and denied a motion for summary judgment of the failure-to-warn claims on preemption grounds. See Ords., Nov. 21, 2025, Dec. 19, 2025. The failure-to-warn claims remain pending and are the subject of the motion for summary judgment that is now before the Court.

III. DISCUSSION

Cooper moves for summary judgment of the failure-to-warn claims on grounds that it was not the NDA holder until Plaintiffs already had their Paragards placed and that it therefore could not have made changes to Paragard's label at any time material to their claims. Cooper also argues that it cannot be held liable on the claims because Florida law imposes product liability only on product designers, manufacturers, distributors, importers, and sellers in the

[4] The master complaint also includes claims of strict liability—Manufacturing Defect (Count III); Negligence—Manufacturing Defect (Count V); Violation of Consumer Protection Laws (Count XII); and Unjust Enrichment (Count XIV). Each of the bellwether plaintiffs agreed to dismiss those claims with prejudice.

chain of distribution, and Cooper did none of those things in relation to Plaintiffs' Paragards. Cooper additionally argues that because the healthcare providers who removed Plaintiffs' Paragards did not testify that any change in the Paragard warnings would have altered their treatment decisions, Plaintiffs cannot establish that a failure to warn was the proximate cause of their injuries. Plaintiffs, in turn, argue that here is a disputed issue of fact about whether Cooper's failure to warn about Paragard's propensity to break caused Plaintiffs' injuries.

To prove a failure-to-warn claim under Florida law, "the plaintiff must show (1) that the product warning was inadequate; (2) that the inadequacy proximately caused her injury; and (3) that she in fact suffered an injury from using the product." Salinero v. Johnson & Johnson, 995 F.3d 959, 964 (11th Cir. 2021) (cleaned up); accord Cates v. Zeltiq Aesthetics, Inc., 73 F.4th 1342, 1347 (11th Cir. 2023); Hoffmann-La Roche Inc. v. Mason, 27 So. 3d 75, 77 (Fla. Ct. App. 2009). Having carefully reviewed Plaintiffs' proffer, the Court does not find evidence sufficient to establish a genuine issue of material fact on the causation element.

It first bears noting that under Florida law, the learned-intermediary doctrine applies, and Cooper's duty to warn was owed to Plaintiffs' physicians and not to Plaintiffs. Florida's learned-intermediary doctrine establishes that a manufacturer of a product, particularly a prescription drug or other specialized product, can fulfill its duty to warn end users of potential dangers by adequately

warning a "learned intermediary," such as a prescribing physician. Mason, 27 So. 3d at 77; Buckner v. Allergan Pharms., Inc., 400 So. 2d 820, 822 (Fla. Ct. App. 1981). The doctrine is based on the premise that the intermediary, due to his or her expertise and knowledge, is in the best position to evaluate the risks and benefits of the product for that particular patient and to convey appropriate warnings to her. Cates, 73 F.4th at 1350; Mason, 27 So. 3d at 77; Buckner, 400 So. 2d at 822. "The patient is expected to and, it can be presumed, does place primary reliance upon [the physician's judgment, and] [t]he physician decides what facts should be told to the patient." Buckner, 400 So. 2d at 823.

Thus, to satisfy the causation element of a claim for failure to warn, the plaintiff must show that her treating physician would have changed her conduct had adequate warnings been provided. Salinero, 995 F.3d at 964-65; Swintelski v. Am. Med. Sys., Inc., 521 F. Supp. 3d 1215, 1221 (S.D. Fla. 2021). The testimony of the physician herself is typically the most direct and probative evidence on the issue, see Hoffmann-La Roche Inc. v. Mason, 27 So.3d 75, 77 (Fla. Ct. App. 2009), but expert testimony regarding how an adequate warning would have affected a reasonable doctor may also be presented, see Dopson-Troutt v. Novartis Pharms. Corp., 975 F. Supp. 2d 1209, 1214 (M.D. Fla. 2013).

The Court recognizes Rickard's argument in briefing on one of the other motions for summary judgment that the learned-intermediary doctrine does not apply because Paragard is a contraceptive product—a category of products where

healthcare providers defer to patients' decisions—and was directly marketed to consumers. Dkt. No. [88] at 22-33. Even so, the Court does not find grounds for excepting contraceptives from Florida's presumption that that the learned-intermediate doctrine applies to prescription drugs. Paragard was available only by prescription and could only be placed and removed by an experienced healthcare provider. Dkt. No. [86-52] ¶ 1. The decision to dispense the drug was therefore subject to the judgment of the doctor. Moreover, Rickard cites no Florida law—only a Massachusetts case—in support of her theory. Dkt. No. [88] at 25. At least two courts applying Florida law have also expressly declined to recognize a direct-to consumer exception to the learned intermediary doctrine. See Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1376-77 (S.D. Fla. 2007); Pringle v. Johnson & Johnson, Case No. 13-81022-CIV, 2020 WL 4501834, at *3, n.5 (S.D. Fla. Jan. 30, 2020) ("Regardless of manufacturer advertising, prescription drugs . . . are federally regulated products that are available to patients only through a learned intermediary."). Thus, the Court finds no basis for disturbing Florida's well-established application of the learned-intermediary doctrine to failure-to-warn claims involving prescription medications.

Accordingly, to establish causation on the failure-to-warn claims Plaintiffs assert against Cooper, they must present evidence sufficient to enable a reasonable jury to find that Cooper's failure to adequately warn their removing physicians led to their injuries. Plaintiffs attempt to do so by arguing that Cooper

knew since the time it acquired the Paragard NDA in 2017—after Plaintiffs had their Paragards placed but before they had them removed—that the label did not adequately warn of breakage. They also contend that Cooper learned shortly after acquiring the NDA that the risk of breakage increased over time, the longer the Paragard was in the woman's body. They argue that Cooper could have—and should have—warned Plaintiffs' removing physicians as soon as they knew of the breakage-related risks via their sales force, Dear Doctor letters, published literature, presentations at medical conferences, and/or press releases. They contend that had Cooper done so, Plaintiffs' physicians would have reviewed the warnings; could have monitored for breakage, communicated the risk to Plaintiffs, and taken steps to "mitigate the risk at the time of removal, including having an ultrasound to assess Paragard's position, location and/or whether it is intact"; and may have recommended early removal. Dkt. No. [78] at 29-30; Dkt. No. [118] at 2-9. Plaintiffs also aver that Rickard's removing physician testified that "[h]ad [she] known of Paragard's true risk of breakage, she would have been on the lookout just like she was with embedment." Dkt. No. [78] at 30.

Most of these allegations go to the adequacy of the warning, not causation. For the purposes of this Order, the Court presumes that the warnings were inadequate and that Cooper had a means of informing Plaintiffs' removing physicians of the warnings but failed to do so. This leaves Plaintiffs' allegations regarding the testimony of Rickard's removing physician and their allegations

that proper warnings would have caused the physicians to monitor for breakage, discuss the breakage risk with Plaintiffs, and take steps to mitigate breakage risk at the time of removal by removing the Paragard early or conducting an ultrasound at the time of removal.

However, Plaintiffs' allegations are not grounded in any evidence. Plaintiffs' cited physician testimony does not in fact state that she would have been more attentive if she had known of Paragard's true breakage risk. See Dkt. No. [78] at 30 (citing Deposition of Niloufer Kero ("Kero Dep.") at 75:25-76:8). Instead, the physician testified in that portion of the deposition that there was no resistance during her first attempt to remove Ms. Rickard's Paragard:

> Q Sitting here today, do you recall whether or not you encountered any difficulty or resistance while you were removing the Paragard from Ms. Rickard?
>
> A No. My record says it was – procedure was tolerated well, and my record does not say I encountered any difficulty. So from my record, it was easy removal.
>
> Q If you -- if you had encountered any resistance or difficulty removing the Paragard –
>
> A I would have stopped.
>
> Q You would have stopped. And why would you have stopped?
>
> A Well, because if -- it probably is embedded or something inside. So if I am -- I would break the string, so I would have sent her for an ultrasound at that point.

Kero Dep. at 75:17-76:8. Thus, the cited testimony does not support causation on the failure-to-warn claims asserted against Cooper.

Plaintiffs' other allegations are equally unsupported, as Plaintiffs do not cite any physician testimony or other expert testimony to show that enhanced warnings would have caused a reasonable physician to warn Plaintiffs that their already-inserted Paragards could break or to recommend imaging, other monitoring, or early removal. Nor do Plaintiffs show evidence that imaging, other monitoring, or early removal would have prevented their injuries. Thus, Plaintiffs have not supplied evidence sufficient to enable a reasonable jury to determine that Cooper's alleged failure to warn was the proximate cause of their injuries.

IV. CONCLUSION

In accordance with the foregoing, Cooper's motion for summary judgment of the failure-to-warn claims of bellwether plaintiffs Pauline Rickard, Melody Braxton, and Alisa Robere is **GRANTED**. The Clerk is **DIRECTED** to terminate submission of Cooper's motion for summary judgment. Because this Order and the Order dismissing the design-defect claims asserted against Cooper dispose of all of the substantive claims asserted against the Cooper by the bellwether plaintiffs, the Clerk is further **DIRECTED** to terminate Cooper as a Defendant in each of the bellwether cases.

IT IS SO ORDERED this 23rd day of December, 2025.

LEIGH MARTIN MAY
UNITED STATES DISTRICT JUDGE